FDA/National Transportation Safety Board Joint Public Meeting
Transportation Safety and Potentially Sedating or Impairing Medications

DRAFT

Opening Remarks

B.A.Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration

Washington, D.C.
November 14, 2001

- Good morning.

- First, let me acknowledge the important role the NTSB plays in our nation's transportation safety issues, and particularly over the last few days--the heroic effort you're making to investigate the tragic plane crash in New York City yesterday.

- As devastating as that accident is, your quick work to investigate the cause has helped to calm Americans' immediate fears. Although the precise cause of the crash is not yet known, it helps to know that terrorism appears to be pretty far down on the list of possibilities.

- We certainly wish you every success in that ongoing investigation.

- We're happy to co-sponsor this first ever FDA/NTSB joint public meeting. I'm glad to see our two organizations take this opportunity to work together to look at the role of sedating or impairing medications in accidents and related injuries.

- I'd like to thank Marion Blakey, the recently appointed chairman of the National Transportation Safety Board, and Dr. Vernon Ellingstad and his staff at the NTSB, for assisting FDA in putting this meeting together. And thanks to Dr. Ellingstad, and Dr. Steve Galson from FDA, for co-chairing the meeting.

- I'm pleased to see the level and range of expertise assembled here today on our panels and as witnesses to consider the issues in front of us. Thank you all for being here.

- The FDA is very supportive of the NTSB's efforts to improve the safety of our nation's transportation operators and we look forward to being a part of that

effort. As Dr. Henney indicated last year, we do take this issue seriously. Today's workshop demonstrates our commitment to consider all perspectives—including those of the transportation industry, other government agencies and the public. We will also work with the pharmaceutical industry when considering recommendations related to labeling changes.

- What are the issues we hope to address today and tomorrow?

    1. First, how can we increase awareness of the public about the possible impairment caused by certain prescription and OTC drug products?

    2. How can we identify those products that may cause impairment?

    3. How can we help the public avoid taking products that may cause impairment when they'll be driving?

    4. Would relabeling those prescription or OTC products help?

- What do we hope to accomplish in these two days?

    1. By looking at the data available today—we hope to define the magnitude of the public health issue--both for transportation operators, and for those with whom they share the roads, rails, skies, and waterways.

    2. We'd like to look at possible mechanisms to screen for effects on driving--perhaps by looking at well-established assessment methods to see if they could be used to evaluate operators taking potentially problematic medications.

    3. We want to identify the best ways to communicate the potential risks to the public. If we decide that labeling modifications are one effective way to accomplish this, what changes should be made so that labeling will be more informative to the user?

- In closing, let me say that to the extent that drugs we've approved are contributing to errors made by vehicle operators—we're concerned. I assure you that we will take seriously, and respond to, the recommendations that come out of this meeting.

- The issues are complex, but they're not insurmountable. Let's work together to find the solutions.

- Thanks to all of you for participating in this meeting and for contributing your time, expertise, and creativity. I'm looking forward to a productive session.